

THE SOCIETY OF THORACIC SURGEONS (STS) STATEMENT REGARDING TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

FOOD AND DRUG ADMINISTRATION
CIRCULATORY SYSTEM DEVICES PANEL OF THE MEDICAL
DEVICES ADVISORY COMMITTEE
June 13, 2012

Jeffrey B. Rich, M.D.
President
The Society of Thoracic Surgeons

The mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.



Disclosures



Concept for Introduction of TAVR Into the U.S.

"Rational Dispersion"

- Coined by Ralph Brindis, Past President ACC, Spring 2011- to describe a methodology for the introduction of new technology into clinical medicine.
- "Rational Dispersion" of TAVR into centers with sufficient experience and patient volume to maintain the reported results of the PARTNER Trial in inoperable and/or high risk patients with aortic stenosis.





Rational Dispersion for the Introduction of Transcatheter Valve Therapy

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David R. Holmes Jr, MD

JAMA, November 16, 2011—Vol 306, No. 19



Rational Dispersion of New Medical Devices





Concepts for the "Rational Dispersion" of TAVR Technology

- Qualified Institutions
- Multidisciplinary Heart Team
- National Valve Registry



STS and ACC Professional Society Joint Initiatives

- Professional Society Overview
- Joint Testimony Before FDA Expert Panel
- Expert Consensus Document (12 societies)
- Joint Educational Courses
- Joint Operator and Credentialing Guidelines (4 societies)
- Formation of a National TVT Registry for TAVR
- Request for National Coverage Determination



Professional Society Involvement Timeline

- July 20, 2011: Testimony by STS and ACC in Public Session of FDA Expert Panel
- September 22, 2011: Request for National Coverage Determination
- November 2011–March 2012: Peer Reviewed Publications
 - Professional Society Overview
 - Expert Consensus Document
 - Center and Operator Credentialing Guidelines
- December 1, 2011: TVT Registry
- May 1, 2012: NCD Issued to cover any FDA approved Indication

SPECIAL REPORT FROM THE SOCIETY OF THORACIC SURGEONS

Transcatheter Valve Therapy: A Professional Society Overview from the American College of Cardiology Foundation and The Society of Thoracic Surgeons

Writing Committee Members: David R. Holmes, JR, MD, FACC, ACCF President, Michael J. Mack, MD, FACC, STS President

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EXPERT CONSENSUS DOCUMENT

Transcatheter Valve Therapy

A Professional Society Overview from the American College of Cardiology Foundation and the Society of Thoracic Surgeons

Writing Committee Members David R. Holmes, JR, MD, FACC, ACCF

President*

Michael J. Mack, MD, FACC, STS President*

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Multisociety (AATS, ACCF, SCAI, and STS) Expert Consensus Statement: Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement, Part 1: Transcatheter Aortic Valve Replacement

Carl L. Tommaso, 1* MD, R. Morton Bolman, III, 2 MD, Ted Feldman, 3 MD, Joseph Bavaria, 4 MD, Michael A. Acker, 4 MD, Gabriel Aldea, 5 MD, Duke E. Cameron, 6 MD, Larry S. Dean, 5 MD, Dave Fullerton, 7 MD, Ziyad M. Hijazi, 8 MD, Eric Horlick, 9 MD, D. Craig Miller, 10 MD, Marc R. Moon, 11 MD, Richard Ringel, 6 MD, Carlos E. Ruiz, 12 MD, PhD, Alfredo Trento, 13 MD, Bonnie H. Weiner, 14 MD, and Evan M. Zahn, 15 MD



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September 22, 2011

Louis Jacques, M.D., Director Coverage & Analysis Group, OCSQ Centers for Medicare and Medicaid Services 7500 Security Boulevard, C1-14-15 Baltimore, Maryland 21244

- Qualified Institutions
- Training/Credentialing
- Multidisciplinary Heart Team
- Technical Participation by both Cardiac Surgeon/Cardiologist
- National TVT Registry

FORMAL REQUEST FOR A MEDICARE NATIONAL COVERAGE DETERMINATION (NCD)

Transcatheter Aortic Valve Replacement (TAVR) Procedures

Sincerely

Michael J. Mack, M.D.

President

The Society of Thoracic Surgeons

David R. Holmes, Jr., M.D., F.A.C.C.

President

American College of Cardiology

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TAVR NCD Highlights

TAVR is covered for the treatment of severe aortic stenosis when furnished according to an FDA approved indication when 2 cardiac surgeons have independently examined the patient and the patient is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals that includes a cardiothoracic surgeon and a cardiologist.

a cardiologist.			
Requirements	Requirements TAVR must be furnished in a hospital with the appropriate infrastructure		
Institution	Without TAVR experience	With TAVR experience	
	• ≥ 50 total AVR/yr. including ≥ 10	• \geq 20 total AVR/yr. or \geq 40 AVRs	
	high risk patients	every 2 years	
	• ≥ 2 physicians with cardiac surgery	 ≥ 2 physicians with cardiac surgery 	
	privileges	privileges	
	• ≥ 1000 catheterizations per year,	 ≥ 1000 catheterizations per year, 	
	including ≥ 400 percutaneous	including ≥ 400 percutaneous	
	coronary interventions (PCIs) per year	coronary interventions (PCIs) per year	
Operator	HEART TEAM with TAVR experience		
	The HEART TEAM must include a cardiovascular surgeon and an interventional cardiologist		
	whose combined experience maintains the following:		
	• ≥ 20 TAVR procedures in the prior year or		
	• ≥ 40 procedures in the prior 2 years and		
	Additional members of the heart team such as echocardiographers, imaging specialists, heart		
	failure specialists, cardiac anesthesiologists, intensivists, nurses, and social worker		
	Cardiovascular Surgeon without TAVR experience		
	• ≥ 100 AVR / career including 10 high risk patients; OR		
	• ≥ 25 AVR / year or 50 AVR in 2 years; OR		
	• \geq 50 AVR in 2 years; and which include at least 20 AVRs in the last year prior to TAVR		
	initiation		
	Interventional Cardiologist without TAVR experience		
	Professional experience with 100 structural heart procedures lifetime or		
	30 left-sided structural procedures per year of which 60% should be balloon aortic		
	valvuloplasty (BAV). Atrial septal defect and patent foramen ovale closure are not		
	considered left-sided procedures		
Registry	The heart team and hospital must participate in a prospective, national, audited registry that		
	consecutively enrolls TAVR patients, accepts all manufactured devices, follows the patient for at		
	least one year, and complies with relevant patient privacy protections.		



STS-ACC National TVT Registry The Vision

- Creation of a generic platform
- Infrastructure for:
 - Pre market IDE device submission
 - Post market surveillance
 - "Off indication" evaluation
 - Usable for different devices and device iterations
- Develop comprehensive infrastructure for disease management
 - Comparative effectiveness analysis
 - Cost effectiveness research
 - Appropriateness of care analysis
 - Quality monitoring
 - Performance improvement opportunity
 - Observational and hypothesis-driven studies of "real world" practice
 - Clarify proper indications for TAVR



STS-ACC National TVT Registry What Is It?

- National Registry of ALL TAVR
- Joint Program
 - STS Adult Cardiac Surgery Database
 - Present in 95% of the >1,100 U.S. Heart Surgery Centers
 - >4 Million records
 - ACCF-NCDR
 - Present in 80% of ~1,500 U.S. Interventional Catheterization Labs
 - >7 Million records
- New TAVR registry to be harmonized with both databases
- Linkage with CMS administrative database



Summary

- Professional societies have been instrumental in the introduction of TAVR into the U.S.
- Multi-stakeholder cooperation has been key in successful launch
- National TVT registry has been constructed and is actively enrolling patients
- NCD has mandated national registry enrollment
- PAS-2 for PARTNER B is nested in the TVT Registry